IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Miri Seiberg et al.	Attorney Docket No.: JBP-438
Serial No.:	09/206,249	Art Unit: 1655
Filed :	December 7, 1998	Examiner: Michael V. Meller
For :	METHODS FOR REGULATING PHAGOCYTOSIS AND ICAM-1 EXPRESSION	

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Commissioner for Patents
Alexandria, VA 22313-1450

CORRECTED APPEAL BRIEF

This Corrected Appeal Brief is respectfully submitted in response to the Office Action of February 25, 2009. Corrections appear in the following sections: (i) the Real Party in Interest was inadvertently erroneously given as "McNeil-PPC, Inc.", but has now been corrected to indicate that the Real Party in Interest is Johnson & Johnson Consumer Companies, Inc.; and (v) in response to the Office Action of February 25, 2009, the Summary of the Claimed Subject Matter has been supplemented with references to the specification by page and line number to show where the support for the subject matter defined in the independent as well as the dependent claims can be located.

i. Real Party in Interest

Johnson & Johnson Consumer Companies, Inc., a New Jersey corporation, is the real party in interest.

ii. Related Appeals and Interferences

None.

iii. Status of Claims

Claims 75-84 are pending in the case. Claims 1-74 and 85 have been canceled. Claims 75-84 have been finally rejected on January 22, 2008 and this Appeal is taken from the rejection of these claims.

iv. Status of Amendments

An Amendment was filed on August 15, 2008 in response to the Final Rejection mailed on March 20, 2008.

v. Summary of Claimed Subject Matter

As fully supported in Appellant's Specification, the claimed invention of independent Claim 75 is directed to a topical method of decreasing phagocytosis or ICAM-1 expression in a patient having one or more of the conditions consisting of pulmonary emphysema, immunological lung disorders, periodontal disease, atherosclerotic plaques, Mid-dermal elastosis, pigmentation disorders, psoriasis, eczema and Acne vulgaris, comprising applying topically to an affected organ of said patient a therapeutically phagocytosis- or ICAM-1 decreasing effective amount of composition containing active trypsin inhibitory activity comprising a non-denatured soy extract

having active trypsin inhibitory activity. Claim 75 is the only independent claim on appeal.

Support for the subject matter of the independent claim may be found in the Specification as follows:

Claim 75. A topical method of decreasing phagocytosis or ICAM-1 expression in a patient having one or more of the conditions (p. 8, l. 4-25) consisting of pulmonary emphysema (p. 2, l. 23), immunological lung disorders (p. 2, l. 30-33), periodontal disease (p. 3, l. 6), atherosclerotic plaques (p. 4, l. 6), Mid-dermal elastosis (p. 5, l. 10), pigmentation disorders (p. 5, l. 16-20), psoriasis (p. 5, l. 30-34), eczema (p. 1, l. 12-16) and Acne vulgaris (p. 6, l. 1), comprising applying topically to an affected organ of said patient (p. 21, l. 19-21, p. 22, l. 6-9) a therapeutically phagocytosis- or ICAM-1 decreasing effective amount of composition (p. 51, claim 2) containing active trypsin inhibitory activity (p. 16, l. 12-21) comprising a non-denatured soy extract having active trypsin inhibitory activity (p. 16, l. 20-21).

Claim 76. The method of claim 75, wherein the composition inhibits the PAR-2 pathway. (p. 17, l. 12-25)

Claim 77. The method of claim 75, wherein the composition comprises a soybean extract comprising a serine protease inhibitor. (P. 17, l. 16-25)

Claim 78. The method of claim 77, wherein the soybean extract contains soybean trypsin inhibitor. (p. 11, l. 12-14, p. 16, l. 13-15, Figures 3, 4A, 5)

Claim 79. The method of claim 75, wherein the affected organ contains PAR-2-expressing cells. (p. 6, l. 13 – p. 7, l. 2, p. 20, l. 21-29)

Claim 80. The method of claim 79, wherein the affected organ contains cells selected from the group consisting of a keratinocyte, a fibroblast, and a professional phagocytic cell. (p. 20, l. 21-29)

Claim 81. The method of claim 80, wherein the affected organ contains keratinocytes. (p. 20, l. 23)

Claim 82. The method of claim 80, wherein the affected organ contains fibroblasts. (p. 20, l. 23)

Claim 83. The method of claim 80, wherein the affected organ contains professional phagocytic cells. (p. 20, l. 24)

Claim 84. The method of claim 75, wherein the affected organ is a human organ.(p. 20, l. 29, Example 11, p. 38, l. 5-35)

vi. Grounds of Rejection to be Reviewed on Appeal

1. Claims 75-84 under 35 U.S.C. 102(b) were rejected as being anticipated by JP Patent Application No. Hei-8-143442 to Matsuura et al (JP '442) (hereinafter, "Matsuura").

2. Claims 75-84 under 35 U.S.C. 102(a) were rejected as being anticipated by JP Patent No. 410226642 (abstract) (hereinafter, "'642 Patent").

vii. Argument

1. The rejection of Claims 75-84 under 35 U.S.C. §102(b) as being anticipated by JP Patent Application No. Hei-8-143442 to Matsuura et al (JP '442) (hereinafter, "Matsuura"). is improper and without basis and should be overruled.

Under 35 U.S.C. §102(b), a person "is entitled to a patent unless…the invention was patented or described in a printed publication or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United

States…" [35 U.S.C. §102(b)] In order to support a rejection based upon anticipation by a reference under 35 U.S.C. §102(b), "[a] single prior art reference anticipates a patent claim if it expressly or inherently describes *each and every* limitation set forth in the patent claim." *Verdegall Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, (Fed. Cir. 1987) (emphasis added). A reference relied upon as anticipatory "must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." *PPG Industries, Inc. v. Guardian Industries Corporation*, 75 F.3d 1558, 1566 (Fed. Cir. 1996).

While it has been found that a "single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim" *Trintec Industries, Inc. v. Top-U.S.A. Corporation*, 295 F.3d 1292, 1295 (Fed. Cir. 2002), demonstrating inherency "requires that the missing descriptive material is '*necessarily present*,' not merely probably or possibly present, in the prior art." *Trintec Industries, Inc. v. Top-U.S.A. Corporation*, 295 F.3d 1292, 1295 (Fed. Cir. 2002). (emphasis added)

Turning now to the cited prior art references, the Matsuura abstract relates to an "external preparation for skin blended with a water extract liquid of soybeans…blended with a soaked liquid of whole soybeans, dehulled soybeans or defatted soybeans, an ultrafiltrate of soymilk or a concentrated liquid of whey." [Matsuura, p. 2, Abstract]

Matsuura describes the means by which the preparation is made as follows:

> …Whole soybeans were heated with hot air at 75°C, and then pressed and dehulled with a roller. Then, hulls and embryonic axes were removed, whereby deulled soybeans each of which was divided into two pieces were obtained. These dehulled soybeans were ground while adding 10 times volume of cold water (5°C) thereby to obtain mashed soybeans. The resulting mashed soybeans were heated at 100°C for 30 seconds, and then cooled to 80°C, and solid-liquid separation was carried out using a screw decanter, whereby soymilk was obtained. The obtained soymilk was degassed, and thermal sterilization at 120°C for 3 minutes was carried out. Then, the concentration of proteins was adjusted to 3.5%, and the soymilk was filtered with an ultrafiltration membrane having a fractionation molecular weight of 300,000, and a low molecular weight fraction was collected as a filtrate…[Matsuura, p. 2, ¶0012]

The Final Rejection relied upon Matsuura as teaching:

> …a water extract of soybeans used to treat eczema. Whole soybeans are ground and water is added and then the extract is filtered. The ground matter is heated but to a temperature which could read on 5°C. [Final Rejection, p. 3]

Appellants respectfully submit that nowhere does Matsuura mention explicitly that the soybean extracts described therein contain active soy trypsin inhibitor proteins (hereinafter, "STI"). Thus, the Final Rejection relies upon Matsuura as *inherently* describing the compositions and methods of appellants' invention.

Appellants respectfully submit that, in view of the Declaration of Miri Seiberg dated July 30, 2008 and attached hereto in the Exhibit Appendix, the soybean extract of JP '442 would *not necessarily* contain STI. As set forth in the Seiberg Declaration dated July 30, 2008, the mere process of permitting soybeans to soak in water will not enable STI to diffuse into the soaking liquid. This conclusion is based upon the knowledge of those skilled in the art that, for biological molecules, the coefficients of diffusion normally range from 10^{-11} to 10^{-10} m^2/s. Because the diffusion coefficient of STI is even lower than the normal range of coefficient of diffusion for biological molecules, it is measured not "per second" but "per day" at 24°C. [Seiberg Declaration of July 30, 2008, ¶7] As it is a biological molecule, the diffusion coefficient of STI is thus so low that it is highly unlikely that any significant amount of STI would diffuse from soybeans into soaking liquid in which it resides [Seiberg Declaration of July 30, 2008, ¶¶6, 7].

Furthermore, Matsuura indicates that the soaked soybean material is subjected to high heat, i.e., 80-100°C and then sterilized at 120°C. As set forth in the accompanying Declaration of Robert Zivin dated December 23, 2003 and attached hereto in the Exhibit Appendix, exposure to high heat denatures, and thus deactivates, proteins such as STI. [Zivin Declaration of December 23, 2003, ¶4] Appellants respectfully contend that one of ordinary skill in the art following Matsuura would, therefore, not *necessarily* obtain a soybean extract that contains non-denatured soy trypsin inhibitory activity.

The Final Rejection avers that, should appellants be correct in the assertion that STI would not diffuse into water in which soybeans were being soaked, "…the STI

would still be in the extract thus reading on the claims, since the STI was not diffused as applicant has argued." [Office Action, p. 4]

Appellants respectfully submit that, in accordance with Matsuura, even if the STI remained intact in the soybeans throughout the processing steps described therein, it would not be present in the compositions that Matsuura describes. This is because the compositions described therein contain "*extract liquid of soybeans*" [JP '442 Translation, p. 2, Claim 1] (emphasis added), rather than the soybeans (even the crushed soybeans) themselves. Matsuura states:

> The present inventors focused attention on a *soaked liquid of soybeans*, which is generated as a by-product during the production of tofu, and conducted studies for aiming at making *efficient use of the soaked liquid*…[JP '442 Translation, p. 4, l. 16-19] (emphasis added)

Matsuura, moreover, indicates that the process involves soaking the soybeans at varying temperatures for varying times and then, "[a]fter the soaking, separation into soybeans and soaked liquid is carried out, and *this soaked liquid is used as a raw material*." [Matsuura, p. 7, l. 2-4] (emphasis added). It is not the soybeans, but the *liquid in which they have soaked*, which is the extract utilized in the compositions of Matsuura. Therefore, if the STI does not diffuse out of the soybeans, it remains in the soybeans and will not appear in the extract of the described compositions.

Furthermore, Matsuura indicates that even in the instance in which there is a "protein fraction" generated by a process, this protein fraction is precipitated out of the extract that is to be used in topical compositions, as follows:

> …In the case where whey generated as a by-product during the production of a soy protein isolate is used as a raw material, for example, 10 times volume of water is added to defatted soybeans, the pH thereof is adjusted to 7.5 with sodium hydroxide, and the mixture is stirred at room temperature for 2 hours. Then, insoluble matter (bean curd refuse) is removed by solid-liquid separation, whereby *a protein-containing liquid is obtained. The pH of this liquid is adjusted to 4.5 with hydrochloric acid to allow the proteins to precipitate, and solid-liquid separation into a protein fraction (soy protein isolate) and whey is carried out*. Then, the soluble sugar content in the whey is adjusted and *the whey is mixed with a hydrophilic ointment base*, whereby an external preparation for skin is prepared…[JP '442, p. 8. l. 11-24] (emphasis added)

Thus, appellants respectfully urge that STI would be present in the extract of the process described in Matsuura, it can be seen that the soybean extract to which Matsuura refers is *not* a protein-containing fraction.

Accordingly, appellants respectfully submit that JP '442 does not explicitly or inherently disclose, teach or suggest explicitly or inherently the subject matter of claims 75-84. Appellants therefore respectfully request that the rejection of claims 75-84 under 35 U.S.C. 102(b) as being anticipated by JP 408143442 be overruled.

2. The rejection of Claims 75-84 under 35 U.S.C. 102(a) as being anticipated by JP Patent No. 410226642 (abstract) (hereinafter, "'642 Patent") is improper and without basis and should be overruled.

Under 35 U.S.C. §102(b), a person "is entitled to a patent unless…the invention was patented or described in a printed publication or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States…" [35 U.S.C. §102(b)] In order to support a rejection based upon anticipation by a reference under 35 U.S.C. §102(b), "[a] single prior art reference anticipates a patent claim if it expressly or inherently describes *each and every* limitation set forth in the patent claim." *Verdegall Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, (Fed. Cir. 1987) (emphasis added). A reference relied upon as anticipatory "must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." *PPG Industries, Inc. v. Guardian Industries Corporation*, 75 F.3d 1558, 1566 (Fed. Cir. 1996).

While it has been found that a "single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim" *Trintec Industries, Inc. v. Top-U.S.A. Corporation*, 295 F.3d 1292, 1295 (Fed. Cir. 2002), demonstrating inherency "requires that the missing descriptive material is '*necessarily present*,' not merely probably or possibly present, in the prior art." *Trintec Industries, Inc. v. Top-U.S.A. Corporation*, 295 F.3d 1292, 1295 (Fed. Cir. 2002). (emphasis added)

The '642 abstract relates to an "agent for preventing and treating skin multiplication [sic] disease and a cosmetic material by formulating a genistein active ingredient with a therapeutic agent for skin disease and a cosmetic material." ['642 Abstract]. The abstract further indicates that genistein is obtainable "by synthesis, extraction from soy lees and soy oil, fermentation using microorganisms and also extraction from beans such as soybean and the like." ['642 Abstract]

Appellants respectfully submit that JP '642 does not anticipate the limitations of independent claim 75 as alleged in the Office Action. Appellants respectfully point out that genistein is an isoflavone compound that is *only one component* of soybean extract. Genistein is extracted from soybeans through a process that extracted from the soybeans would not contain STI even at "low concentrations". As set forth in the accompanying Seiberg Declaration dated July 30, 2008, genistein extracted from soybeans at low concentrations (as used by JP '642) will not contain STI activity because genistein, is known to be extracted from soybeans using organic solvents [Seiberg Declaration of July 30, 2008, ¶4]. Soy trypsin inhibitor activity is *denatured* by organic solvents [Seiberg Declaration of July 30, 2008, ¶3].

Furthermore, proteins, including STI, separate out of the organic phase in organic extraction processes while genistein and other isoflavones remain in the organic phase. [Seiberg Declaration, ¶4]. Thus, STI would tend to separate from genistein during the organic extraction process. Even if trace amounts of STI appeared in the organic phase that also contains genistein, such protein molecules would be denatured and, therefore, inactive in the final extract. [Seiberg Declaration, ¶5]

Accordingly, based on the reasons outlined above and the Declarations submitted concurrently herewith, appellants respectfully submit that the '642 Abstract does not explicitly or inherently disclose, teach or suggest explicitly or inherently the subject matter of claims 75-84. Appellants therefore respectfully request that the rejection of claims 75-84 under 35 U.S.C. 102(a) as being anticipated by the '642 Abstract be overruled.

Respectfully submitted,

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Claims Appendix

Claim 75. A topical method of decreasing phagocytosis or ICAM-1 expression in a patient having one or more of the conditions consisting of pulmonary emphysema, immunological lung disorders, periodontal disease, atherosclerotic plaques, Mid-dermal elastosis, pigmentation disorders, psoriasis, eczema and Acne vulgaris, comprising applying topically to an affected organ of said patient a therapeutically phagocytosis- or ICAM-1 decreasing effective amount of composition containing active trypsin inhibitory activity comprising a non-denatured soy extract having active trypsin inhibitory activity.

Claim 76. The method of claim 75, wherein the composition inhibits the PAR-2 pathway.

Claim 77. The method of claim 75, wherein the composition comprises a soybean extract comprising a serine protease inhibitor.

Claim 78. The method of claim 77, wherein the soybean extract contains soybean trypsin inhibitor.

Claim 79. The method of claim 75, wherein the affected organ contains PAR-2-expressing cells.

Claim 80. The method of claim 79, wherein the affected organ contains cells selected from the group consisting of a keratinocyte, a fibroblast, and a professional phagocytic cell.

Claim 81. The method of claim 80, wherein the affected organ contains keratinocytes.

Claim 82. The method of claim 80, wherein the affected organ contains fibroblasts.

Claim 83. The method of claim 80, wherein the affected organ contains professional phagocytic cells.

Claim 84. The method of claim 75, wherein the affected organ is a human organ.

viii. Evidence Appendix

Declaration	Dated	Entered
Declaration of Katharine Martin	02-08-2002	03-18-2002
Declaration of Miri Seiberg	04-22-2003	04-22-2003
Declaration of Robert Zivin	12-23-2003	01-16-2004
Declaration of Miri Seiberg	01-17-2006	01-25-2006
Declaration of Miri Seiberg	07-30-2008	08-15-2008

The foregoing Declarations are filed concurrently herewith in the Evidence Appendix.

ix. Related Proceedings Appendix

Not Applicable.